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Attorneys for Plaintiffs
Southern Research Institute and
Genzyme Corporation

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SOUTHERN RESEARCH INSTITUTE and GENZYME CORPORATION, Plaintiffs, v. ABON PHARMACEUTICALS LLC, Defendant.	Civil Action No. **COMPLAINT** **JURY TRIAL REQUESTED** *Electronically Filed*

Plaintiffs Southern Research Institute ("SRI") and Genzyme Corporation ("Genzyme"), by their attorneys, for their Complaint against Abon Pharmaceuticals LLC ("Abon") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to an Abbreviated New Drug Application ("ANDA") filed by Abon with the United States Food and

Drug Administration ("FDA") for approval to market a generic version of Genzyme's Clolar® drug product.

THE PARTIES

2. SRI is a corporation organized and existing under the laws of Alabama, having its principal place of business at 2000 Ninth Avenue South, P.O. Box 55305, Birmingham, Alabama 35205-5305.

3. Genzyme is a corporation organized and existing under the laws of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme sells drug products containing clofarabine in the United States under the trademark Clolar®.

4. On information and belief, Abon is a corporation organized and existing under the laws of New Jersey, having its principal place of business at 140 Legrand Avenue, Northvale, New Jersey 07647.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

6. This Court has personal jurisdiction over Abon by virtue of its presence and incorporation in New Jersey, its continuous and systematic contacts with New Jersey, and its course of conduct that is designed to cause the performance of acts that will result in foreseeable harm in New Jersey.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b). Abon maintains a substantial presence in this judicial district and has continuous and

systematic contacts with New Jersey. On information and belief, Abon's corporate headquarters and principal place of business is located at 140 Legrand Avenue, Northvale, New Jersey 07647.

THE PATENT

8. United States Patent No. 5,661,136 ("'136 patent") was duly and legally issued on August 26, 1997 to inventors John A. Montgomery and John A. Secrist, III. The '136 patent was assigned to SRI. With patent term extension, the '136 patent will expire on January 14, 2018. At all times from the issuance of the '136 patent to the present, SRI has been the owner of the '136 patent. Genzyme holds exclusive rights from SRI under the '136 patent.

ACTS GIVING RISE TO THIS ACTION

9. By letter dated June 14, 2012, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "Notice Letter"), Abon notified plaintiffs that Abon had submitted ANDA No.204029 to the FDA under section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, importation, use, and sale of 20mg/20ml clofarabine injection ("Clofarabine ANDA Injection") as a generic version of Genzyme's Clolar® drug product.

10. On information and belief, Abon stated in its ANDA that its Clofarabine ANDA Injection is bioequivalent to Genzyme's 20 mL clofarabine Clolar® drug product.

11. Abon's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of Abon's Clofarabine ANDA Injection prior to the expiration of the '136 patent, which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Genzyme's Clolar® drug product.

12. On information and belief, Abon intends to engage in the commercial manufacture, importation, use, and sale of its Clofarabine ANDA Injection promptly upon receiving FDA approval to do so.

13. In the Notice Letter, Abon notified plaintiffs that its ANDA contained a "paragraph IV" certification that in Abon's opinion the '136 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell or importation of Abon's Clofarabine ANDA Injection.

COUNT I
INFRINGEMENT BY ABON OF U.S. PATENT NO. 5,661,136

14. Plaintiffs repeat and reallege the allegations of paragraphs 1- 13 as if fully set forth herein.

15. Abon's submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of its Clofarabine ANDA Injection prior to the expiration of the '136 patent constitutes infringement of one or more of the claims of the '136 patent under 35 U.S.C. § 271(e)(2)(A).

16. Abon's commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection in/into the United States, prior to the expiration of the '136 patent, would constitute infringement of the '136 patent under 35 U.S.C. § 271(a).

17. Abon's ANDA and Abon's intent to engage in the commercial manufacture, importation, use, or sale of its Clofarabine ANDA Injection upon receiving FDA approval create an actual case or controversy with respect to infringement of the '136 patent.

18. Upon FDA approval of Abon's ANDA, Abon will infringe the '136 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell or importing its Clofarabine ANDA Injection in/into the United States, unless enjoined by this Court.

19. Upon FDA approval of Abon's ANDA, Abon will infringe the '136 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

20. Abon had notice of the '136 patent at the time of its infringement. Abon's infringement has been, and continues to be, willful and deliberate.

21. Plaintiffs will be substantially and irreparably harmed if Abon's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully request the following relief:

(a) A judgment declaring that Abon has infringed, and that Abon's making, using, selling, offering to sell, or importing its Clofarabine ANDA Injection will infringe, the '136 patent;

(b) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 204029 under Section 505(j) of the Federal Food, Drug, and Cosmetic Action (21 U.S.C. § 355(j)) be a date no earlier than January 14, 2018, the date on which the '136 patent expires, or the expiration of any other exclusivity to which Genzyme or SRI becomes entitled;

(c) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Abon from making, using, selling, offering to sell, or importing its Clofarabine ANDA Injection in/into the United States until after expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or SRI becomes entitled;

(d) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Abon infringes the '136 patent by engaging in the commercial

manufacture, importation, use, sale, offer to sell or import its Clofarabine ANDA Injection in/into the United States prior to the expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or SRI becomes entitled;

(e) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiffs hereby demand a trial by jury of all issues so triable.

DATED: July 27, 2012	CONNELL FOLEY LLP
	By: s/ *Liza M. Walsh* Liza M. Walsh Christine I. Gannon 85 Livingston Avenue Roseland, New Jersey 07068-1765 (973) 535-0500 lwalsh@connellfoley.com cgannon@connellfoley.com *Attorneys for Plaintiffs* *Southern Research Institute and* *Genzyme Corporation*
Of Counsel: Paul H. Berghoff Paula S. Fritsch McDonnell Boehnen Hulbert & Berghoff LLP 300 South Wacker Drive Chicago, Illinois 60614 berghoff@mbhb.com fritsch@mbhb.com	

RULE 11.2 CERTIFICATION

We hereby certify that the matter in controversy is not the subject of any other action pending in this or any other court.

DATED: July 27, 2012

CONNELL FOLEY LLP

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

DATED: July 27, 2012

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